IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HIGHLY CONFIDENTIAL-TO BE FILED UNDER SEAL
SUBJECT TO PROTECTIVE ORDER

IN RE THALOMID AND REVLIMID LITIGATION	**Civil No. 14-6997 (MCA) (MAH)**

CLASS PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR CLASS CERTIFICATION AND APPOINTMENT OF CLASS COUNSEL

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I. INTRODUCTION

Celgene has successfully monopolized the market for thalidomide (Thalomid) and lenalidomide (Revlimid), two life-saving medications, for at least the last seven years. While Plaintiffs and other members of the proposed Classes have seen price increases of more than [redacted] for Thalomid and [redacted] for Revlimid since the drugs' introduction, Celgene has been unjustly enriched by some [redacted] in profits. To date, at least [redacted] different generic manufacturers have attempted to enter the market, but as a result of Celgene's conduct, no generic alternatives are available.

Plaintiffs now seek certification of the following Classes:

The "Antitrust/Consumer Protection Damages Class" (under Rule 23(b)(3)):

> All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide in any form after November 6, 2010 or lenalidomide in any form after January 29, 2011, in California, the District of Columbia, Florida, Kansas, Maine, Massachusetts, Michigan, Nebraska, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, or Tennessee, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries.

The "Unjust Enrichment Damages Class" (under Rule 23(b)(3)):

> All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide in any form after November 6, 2010 or lenalidomide in any form after January 29, 2011, in California, the District of Columbia, Florida, Kansas, Maine, Massachusetts, Michigan, Nebraska, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, or Tennessee, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Unjust Enrichment Damages Class").

The "Injunction Class" (under Rule 23(b)(2)):

> All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide in any form after November 6, 2010 or lenalidomide in any form after January 29, 2011, in the United States or its territories for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Injunction Class").[1]

[1] Excluded from the Classes are: government entities (except for government-funded employee benefit plans), those who purchased the drugs for purposes of resale or directly from Celgene, fully insured health plans, and "single flat co-pay" consumers who purchased the drugs only via a fixed dollar co-payment that does not vary on the basis of the purchased drug's status as branded or generic. *See* Class Plaintiffs' Motion for Class Certification and Appointment of Class Counsel, for exact language.

As demonstrated below, Plaintiffs have met their burden to satisfy the requirements of Rule 23(a), (b)(2), and (b)(3). There are hundreds of ascertainable members of each of the proposed Classes, and they all share common questions of law and fact. The six named Plaintiffs' claims are typical of other class members and will adequately represent their interests.[2] Further, common issues predominate as to each element of Plaintiffs' claims:

- Plaintiffs will use common evidence to prove that Celgene violated federal and state antitrust, consumer protection, and unjust enrichment laws by engaging in an anticompetitive scheme to monopolize the markets for Thalomid and Revlimid. This evidence will include Celgene's own documents and witness testimony, as well as documents and testimony produced by generic manufacturers that either agreed with Celgene to delay their entry, or that Celgene successfully blocked from entering the market. Proof of Celgene's anticompetitive conduct is the same for all class members.

- Plaintiffs will likewise use common proof to establish that all or virtually all class members were impacted by Celgene's conduct. In addition to documents and other evidence, Plaintiffs have submitted reports by two experts to demonstrate impact on a classwide basis:

  - Luis Molina, a professional in the pharmaceutical industry with substantial experience in product launches of brand and generic drugs, examined the evidence of Celgene's conduct, including Celgene's refusal to supply samples to generic manufacturers while supplying them to clinical researchers, and Celgene's refusal to allow generic manufacturers to utilize its REMS program. In his report, Mr. Molina explains that, but for Celgene's conduct, less expensive generic alternatives to Thalomid and Revlimid would have been available by [redacted] and [redacted], respectively.

  - Dr. Jeffrey Leitzinger, an economist with more than 30 years of experience and the President of Econ One for the last 20 years, reviewed economic literature, forecasts from Celgene and its competitors, data from pharmacies, and publicly available data on benchmark drugs. In his report, Dr. Leitzinger explains that conduct that illegally delays AB-rated generic competition causes average prices paid for the drug at issue to be much higher than they would otherwise be, resulting in overcharges to persons and entities (here, members of the proposed Classes) that paid for the drug. Dr. Leitzinger concludes that proof of the illegality of Celgene's conduct to delay the onset of generic competition is common to the class and sufficient to show widespread antitrust injury.

- Plaintiffs will also show that common proof can be used to calculate damages to members of the proposed Classes. Dr. Leitzinger describes in his report how the results of his model can be used formulaically to calculate damages for each class.

[2] Five plaintiffs filed a Consolidated Amended Complaint on August 1, 2017. On September 28, 2017, New England Carpenters Health Benefits Fund filed a related case in order to join this action as a proposed class representative (17-cv-7637).

A class action is the fairest and most efficient way to adjudicate Plaintiffs' claims. A class action is far superior to the alternative here: hundreds of individual lawsuits, with each plaintiff using the same evidence and expert analysis to address common questions. Therefore, Plaintiffs respectfully request that the Court certify the proposed Classes. In addition, Interim Co-Lead Counsel respectfully request that the Court appoint them as Class Counsel pursuant to Rule 23(g).

II. STATEMENT OF FACTS

A. CELGENE'S SCHEME TO EXCLUDE COMPETITION

1. Celgene Imposes Fifty-Fold Price Increases on Decades-Old Thalidomide

If monopoly power is "the power to control prices,"[3] Celgene went into the pharmaceuticals business to become a monopolist. Former Celgene CEO Sol Barer told the *Wall Street Journal* that he moved the company from industrial chemicals to pharmaceuticals in the early 1990s because "the old focus was 'a lousy business'" since "'[c]hemicals are priced on the cost of ingredients,'" whereas "pharmaceuticals are 'priced on value.'"[4] Despite Barer's optimism, Celgene remained barren of profit until 1999, when, through what Celgene called "medical serendipity," an independent researcher demonstrated that the drug thalidomide had positive effects in treating the blood cancer known as multiple myeloma.[5] Thalidomide was a well-known compound that had been marketed as early as the 1950s as a sleeping pill and cure for morning sickness (later banned by the FDA due to birth defects).[6]

Celgene had already obtained approval to sell thalidomide to treat leprosy.[7] [redacted]

[redacted]

[3] *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966).

[redacted]

[5] Ex. 3, CELM-GILB-000096629, at 6632; Ex. 1, CELM-ZELJ-000028778, at 8779-8783.
[6] Ex. 1, CELM-ZELJ-000028778, at 8780; Ex. 3, CELM-GILB-000096629, at 6632.
[7] Ex. 1, CELM-ZELJ-000028778, at 8780.

did Celgene play any role other than giving the researcher samples of thalidomide.[8]

Nonetheless, the 1999 study proved to be a massive windfall for Celgene. After learning of thalidomide's application to cancer, Celgene adjusted the price of Thalomid—its brand-name for thalidomide—"[redacted][9] In fact, the only "question . . . was whether to double or triple the price immediately or make gradual increases."[10] From 1998 until 2004, Celgene imposed five-fold increases on the price of Thalomid capsules, with prices rocketing from $6 to $29.44 per pill.[11] Celgene extended its monopoly further when, in 2006, it obtained the FDA's approval to market blood-cancer medication Revlimid, a "thalidomide analogue."[12] Since then, Celgene has steadily increased the prices of both drugs at least once a year,[13] with Thalomid prices multiplying by a factor of [redacted][14] and Revlimid prices rising from [redacted] During 2017 alone, a multiple-myeloma patient can expect to spend as much as $138,338.65 for Thalomid and $261,580.90 for Revlimid.[16] Yet over the same period in which Celgene's [redacted] gross profit margins were driven by Thalomid and Revlimid sales, Celgene's cost of manufacturing never exceeded [redacted] per capsule, respectively.[17] Even

[redacted]

[10] Ex. 1, CELM-ZELJ-000028778, at 8781.
[11] *Id.* at 000028779, 28782.
[12] Ex. 7, CELM-NDAR-000077060.
[redacted]
[14] Ex. 88, CELIUB-MYLA-000008236, Ex. 7B (Thalomid NSP Prices by Strength).
[15] *Id.* at Ex. 9B (Revlimid NSP Prices by Strength).
[16] *See* Information for Vermont Prescribers of Prescription Drugs: Thalomid® (thalidomide) capsules, 4/6/2017, *available at* https://www.celgene.com/content/uploads/thalomid-long-form.pdf; Information for Vermont Prescribers of Prescription Drugs: Revlimid® (lenalidomide) capsules, 4/5/2017, *available at* https://www.celgene.com/content/uploads/revlimid-long-form.pdf.
[redacted]

[redacted]

2. Celgene Launches a Multi-Faceted Strategy to Block Generic Competition

As Celgene recently warned its shareholders, "[m]anufacturers of generic drugs are seeking to compete with our drugs and present a significant challenge to us."[19] In 2007, Celgene disclosed to investors, "Our revenues and profits would be negatively impacted if generic versions of [Thalomid or Revlimid] were to be approved and launched."[20] [redacted]

Appreciating the threat of generic competition, Celgene waged an all-fronts campaign to prevent generic drug manufacturers from introducing off-brand versions of Thalomid and Revlimid. Celgene's tactics to foreclose competition have included listing and suing to enforce invalid patents, refusing to sell samples necessary to develop generics, and encouraging the FDA to reject generic applications based on sham safety concerns. Celgene's scheme and the impact on purchasers

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[redacted]

[19] Ex. 12, CELMN-COUO-000050901 at 0921.

[20] Ex. 13, CELM-BROF-000032646, at 32669.

[redacted] xpert Report of Jeffrey J. Leitzinger, Ph.D. (Oct. 2, 2017) ("Leitzinger Report") at ¶¶ 10(b), 16, 26.

[23] *E.g.*, Ex. 17, CELM-COUO-000010677, at 0684.

constitute predominating common evidence that applies equally to all class members.

Plaintiffs are not alone in their effort to hold Celgene accountable. [redacted] pharmaceutical companies have sought to bring generic Thalomid or Revlimid to market—most of which were either sued by Celgene for alleged patent infringement, or sued Celgene for violating antitrust laws (or both).[24] The FDA has announced its intention "to take steps to address" brand-manufacturers' use of their REMS programs "as a basis for blocking generic firms from accessing the testing samples they need,"[25] [redacted]

State and federal competition authorities are investigating Celgene's attempts to suppress competition. [redacted]

[24] *Celgene Corp. v. Dr. Reddy's Labs., Inc.*, No. 16-07704 (D.N.J. Oct. 20, 2016); *Celgene Corp. v. Lannett Holdings, Inc.*, No. 15-00697 (D.N.J. Jan. 30, 2015); *Celgene Corp. v. Natco Pharma, Ltd.*, No. 10-05197 (D.N.J. Oct. 8, 2010); *Celgene Corp. v. Barr Labs., Inc.*, No. 07-00286 (D.N.J. Jan. 18, 2007); *Celgene Corp. v. Lannett Holdings, Inc.*, No. 15-00697 (D.N.J. Jan. 30, 2015); *Mylan Pharm., Inc. v. Celgene Corp.*, No. 14-02094 (D.N.J. Apr. 3, 2014); *Celgene Corp. v. Barr Labs., Inc.*, No. 08-03357 (D.N.J. July 3, 2008); *Celgene Corp. v. Barr Labs., Inc.*, No. 07-04050 (D.N.J. Aug. 23, 2007). *See also* Ex. 22, CELMN-PASM-000030125, at 30210-0218.

[25] U.S. Food & Drug Administration, *FDA Working to Lift Barriers to Generic Drug Competition* (June 21, 2017), *available at* https://blogs.fda.gov/fdavoice/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/

[26] *E.g.*, Ex. 18, CELMN-PASM-000002346; Ex. 19, CELMN-PASM-000001608; *see also* Appendix A (listing Celgene correspondence with generic manufacturers and the FDA).

[27] *See* Celgene Corp. Form 10-K, at 113 (February 10, 2016), *available at* http://files.shareholder.com/downloads/AMDA-262QUJ/4173737449x0xS816284-17-3/816284/filing.pdf (stating that the FTC and Connecticut AG investigations are ongoing); Ex. 20, CELMN-PASM-000013291 [redacted]

[redacted] One multiple-myeloma patient told an investigative congressional committee that Celgene "is using the bogus pretext of Risk Evaluation and Mitigation to unlawfully deny samples to generic manufacturers in order to prevent them from developing a cheaper alternative," thus "ripping off patients and taxpayers while blocking market competition."[29] Congress has taken note "that certain brand drug companies [are] misusing their [controlled-distribution programs] to withhold access to drug samples for bioequivalence testing and generic drug development."[30] Despite the intervention of state and federal regulators, the concerns of Congress, and the attempts of more than [redacted] separate manufacturers to obtain samples from Celgene and enter the relevant markets,[31] Celgene's efforts to stymie generic entry continue. No generic equivalent of Thalomid or Revlimid exists.[32]

B. CELGENE LISTS INVALID DISTRIBUTION PATENTS TO BLOCK ENTRY

Even after learning that it stood to profit from the use of thalidomide to treat cancer, Celgene still had a problem: it could not stop competitors from marketing thalidomide because the patents on the drug had expired.[33] Unable to exclude competition by patenting the compound itself, Celgene did the next-best thing by controlling the means of *distributing* the drug.[34]

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[28] Ex. 21, CELMN-PASM-000036899, at 6900.

[29] "Examining the Impact of Voluntary Restricted Distribution Systems in the Pharmaceutical Supply Chain," U.S. House of Representatives Committee on Oversight and Government Reform, Subcommittee on Health Care, Benefits, and Administrative Rules, 115th Congress (2017), *available at* https://oversight.house.gov/wp-content/uploads/2017/03/David-Mitchell-OGR-Testimony.pdf (statement of proposed class representative David Mitchell) [hereinafter "Mitchell Testimony").

[30] The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition: Hearing Before the Antitrust Subcommittee of the Senate Judiciary Committee, 114th Congress (2016), *available at* https://www.judiciary.senate.gov/download/06-21-16-grassley-statement (statement of Sen. Grassley).

[31] *See* Ex. 22, CELMN-PASM-000030125, at 30210-0218 (Appendix A and Response to Interrogatory No. 2) (listing [redacted] companies that had attempted to buy Thalomid or Revlimid from Celgene as of 2010).

[32] *See* U.S. Dept. of Health and Human Services, FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (2017) ("Orange Book"), at 3-227, 3-375, *available at* https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf.

[33] Ex. 23, CELM-HUGR-000003930, at 3957.

[34] *See* Ex. 1, CELM-ZELJ-000028778, at 8780 ("Since thalidomide had been around for decades and the

In this effort, Celgene was inadvertently assisted by a regulatory system called "REMS"—Risk Evaluation and Mitigation Strategy. Authorized by the Food and Drug Administration Amendments Act (FDAAA) of 2007, REMS programs impose conditions on the distribution and/or administration of drugs that are determined by the FDA to involve significant risks to patients.[35] Because thalidomide was known to cause birth defects if consumed during pregnancy,[36] Celgene proposed a REMS program for Thalomid (called "STEPS") when it sought FDA approval.[37] [redacted]

1. Celgene Obtains Duplicative, Obvious Patents On Its REMS Program By Failing to Disclose Relevant Prior Art to the U.S. Patent Office

According to Celgene's former CEO, Celgene knew that [redacted] To prevent competition, Celgene immured its REMS in layers of duplicative patents claiming obvious ideas. Between 1998 and 2012, Celgene filed for and obtained from the U.S. Patent and Trademark Office (PTO) fourteen patents on its REMS program. *See* Appendix B. Celgene listed these patents in the FDA's "Orange Book" to deter would-be competitors from developing generic equivalents.[40] Many of these patents were so similar that Celgene did not even

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composition couldn't be patented, Celgene would eventually patent this system of controlling distribution.").

[35] *See* 21 U.S.C. § 355-1(a)(1).

[36] Ex. 24, CELM-GILB-000096634, at 6632.

[redacted]

[40] *See* Orange Book, Patent and Exclusivity Information Addendum, at 122-124 of 237. The Orange Book is a resource published by the FDA in which the manufacturer of a brand drug may list any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer. 21 U.S.C. § 355(b)(1).

bother changing the title or abstract describing the patent.[41]

Celgene's REMS systems[42] amount to the following basic requirements: (1) "[c]linicians who wish to prescribe thalidomide must be registered in" Celgene's system and must "agree to prescribe the drug" in accordance with Celgene's "patient eligibility and monitoring procedures;" (2) "[p]harmacies must also register and agree to comply with patient identification and monitoring criteria;" (3) patients must receive materials counseling them on the risks of being treated with thalidomide and how to avoid becoming pregnant during treatment; (4) "[w]omen of childbearing potential must agree to undergo pregnancy testing" before and during treatment; and (5) patients must complete a confidential survey.[43] This REMS was derivative of restricted-distribution programs for other drugs that had been on the market for years.

When Celgene submitted the STEPS program for approval by the FDA, the company acknowledged it "is based on two existing safety models currently in use for [Accutane] and [Clozaril]…"[44] and asserted in published articles that both programs were "successful" and "provided guides" for controlling and monitoring access to thalidomide.[45] Celgene vaunted the similarities, underscoring in FDA submissions that [redacted]

Celgene's candor ***disappeared*** when it came to persuading the PTO that its REMS were

[41] *See, e.g.*, Appendix B Rows 3, 6, 7, 9, 12, 13.
[redacted]
[43] Ex. 29, CELMN-FREJ-000104141.
[44] Ex. 30, CELM-NDAT-000023723, at 3733; [redacted]
[45] Ex. 31, CELIUB-MYLA-000016180 at 6264; *see also* Ex. 32, CELM-KAMJ-000000363; Ex. 33, CELIUB-MYLA-000092930 [redacted]
[46] Ex. 30, CELM-NDAT-000023723, at 4009.

sufficiently novel to deserve fourteen patents. Celgene repeatedly failed to disclose the very materials that it relied on in presenting its program to the FDA and other similar prior art, including the Clozaril Patient Monitoring Service and numerous published works describing the features of REMS programs similar to Celgene's. Celgene also omitted that its REMS system was obvious to professionals in the field. [redacted] As the U.S. Patent Trial and Appeal Board (PTAB) later found in invalidating the first of Celgene's REMS patents as obvious, "[w]hen it benefitted [Celgene's] interests before the FDA, [Celgene] freely admitted that its 'plan [for thalidomide] is built on experience with restrictions on such other drugs with severe adverse effects as Accutane . . . and Clozaril.'"[51]

[47] Ex. 34, CELM-NDAT-000122775, at 2821.
[48] Ex. 30, CELM-NDAT-000023723, at 4009.
[49] [redacted]
[51] *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01092, at 24 (P.T.A.B. Oct. 26, 2016).

2. Celgene Admits Its REMS Patents Are Weak

As early as 2007, market analysts warned Celgene's investors that "thalidomide's composition-of-matter patents have all expired," its "patents for distribution, usage and formulation are less robust than patents on composition of matter, and we have seen cases in which patents on composition of matter have not held up[.]"[52] [redacted] Indeed, in *Alice Corp. v. CLS Bank Int'l*, the Supreme Court held that the use of a computer system to manage escrow debts (like Celgene's use of a computer system to track patients and prescribers), was not patentable. 134 S. Ct. 2347 (2014).

Knowing that its REMS patents are highly vulnerable, Celgene has studiously avoided triggering a judgment on their validity. Despite filing at least six patent infringement lawsuits, Celgene has not litigated a single one to judgment.[54] For example, after competitor Natco filed an FDA application to market generic Revlimid, Celgene sued it for infringing its patents, then dropped its claims as soon as a settlement materialized delaying Natco's entry.[55] Industry observers praised Celgene's "shrewd move" since "the odds are that [Celgene] will lose," and a settlement "would make sense for Celgene in light of its weak patent position, since Natco and Celgene would both be better off stopping the litigation . . . before the arguments against the patents are made public."[56]

3. Celgene Patents Revlimid—A Virtual Clone of Thalomid

Recognizing that its REMS distribution-system patents were weak, but unable to patent

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[52] Ex. 23, CELM-HUGR-000003930, at 3957; Ex. 36, CELM-HUGR-000004746, at 4863.
[53] Ex. 37, CELM-FTCV-000004274, at 4275.
[54] *See supra* n. 24 (listing patent infringement and/or antitrust actions).
[55] Complaint, *Celgene Corp. v. Natco Pharma, Ltd.*, 10-05197 (D.N.J. Oct. 8, 2010).
[56] Ex. 38, CELMN-PASM-000032459, at 2461. Natco benefits from its agreement not to invalidate Celgene's patents, as its agreement with Celgene allows it to share Celgene's monopoly profits. Celgene benefits from continued patent protection, despite industry predictions (after the European Patent Office revoked a Celgene patent on a polymorph of lenalidomide for obviousness) that Celgene's "*entire suite of patents*" protecting Revlimid would be invalidated if challenged. Ex. 109, ThalRev_OC_000016.

thalidomide itself, Celgene sought to shore up its monopoly by patenting a virtual clone of the thalidomide molecule. [redacted]

Initially, Celgene embraced Revlimid's similarity to thalidomide, describing it as one of several "thalidomide analogues" having "structural similarity with thalidomide."[59] [redacted][61]

C. CELGENE PREVENTS COMPETITION BY FILING SHAM CITIZEN PETITIONS AND REFUSING TO SELL SAMPLES TO GENERIC COMPANIES

1. Celgene [redacted] Efforts to Block Entry

In addition to listing unenforceable patents, Celgene has suppressed competition by abusing several aspects of the FDA's regulatory regime governing the approval of generic drugs. Any person may file an FDA "Citizen Petition" to formally state concerns regarding any drug, requiring the FDA

[57] Ex. 39, CELM-DANP-000043976, at 3977.
[58] Ex. 40, CELM-BOCT-000050988, at 0994.
[59] Ex. 7, CELM-NDAR-000077060, at 7064.
[60] *See, e.g.*, Ex. 40, CELM-BOCT-000050988, at 0994 [redacted]
[61] Ex. 41, CELM-ZELJ-000024798, at 4799 [redacted]

to evaluate concerns before taking action on their subject matter.[62] Thus, filing Citizen Petitions can directly impact and delay FDA approval of generic drugs.

In 2006, in response to news that competitor Barr Pharmaceuticals had filed an application with the FDA to market a generic version of Thalomid, [redacted]

Although Celgene's petition claimed that the FDA should refrain categorically from approving any generic on safety grounds, Celgene's safety argument was pretextual. Most damning, the petition's contention that Barr and other generic manufacturers were somehow incapable of distributing thalidomide safely [redacted] One patient testified before Congress that "[t]he counseling under [Celgene's REMS] program consisted of a nurse reading a list of cautions to me. The survey was an automated phone call—press one for yes and two for no. The whole process

[62] 21 C.F.R. § 10.30.

[redacted]

[64] *Id.* at 50:24-51:9.

[65] *Id.* at 52:5-53:22.

[redacted]

took 5-10 minutes. It could have been easily duplicated by any generic manufacturer. It wasn't rocket science."[69] [redacted]

These admissions and Celgene's willingness to license its REMS program to generic manufacturers and foreign companies for use in non-competing products contradict Celgene's insistence that it is somehow unique in its ability to use its controlled-distribution programs. [redacted] Nonetheless, Celgene's petition had the desired effect of delaying—and ultimately obviating—FDA's review of Barr's Thalomid generic. [redacted]

2. Celgene Refuses Generic Companies' Requests to Buy Reference Samples

The maker of a generic drug must demonstrate that its product is "bioequivalent" to an FDA-approved drug.[74] Proving bioequivalence requires generic manufacturers to obtain samples of the approved drug and to perform tests comparing it to the proposed generic.[75] Because Celgene controls

[69] *See* Mitchell Testimony, *supra* n. 29
[70] Ex. 45, CELIUB-MYLA-000080224, at 5. [redacted]
[73] Ex. 47, CELM-THOF-000015242, at 5243.
[74] 21 C.F.R. § 314.94(a)(7). [redacted]

the U.S. market for thalidomide and lenalidomide, generic companies in need of samples for bioequivalence testing have to get them from Celgene.[76]

[redacted]: Celgene learned to use its REMS as a pretext for refusing to provide samples of both drugs to competitors.[79] Indeed, each time a generic company sought samples, Celgene systematically delayed its responses and issued ever-multiplying demands for evidence that the company would handle the drug samples safely.

[redacted] For example, Celgene used its purported safety concerns to deny competitor Mylan Pharmaceuticals' requests to buy Thalomid samples for almost ***five years*** before Mylan gave up, and to delay selling Revlimid samples for another year before Mylan finally sued, alleging antitrust violations.[83] [redacted]

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[76] [redacted]

[77] Ex. 49, CELIUB-MYLA-000004900, at 4901-02.

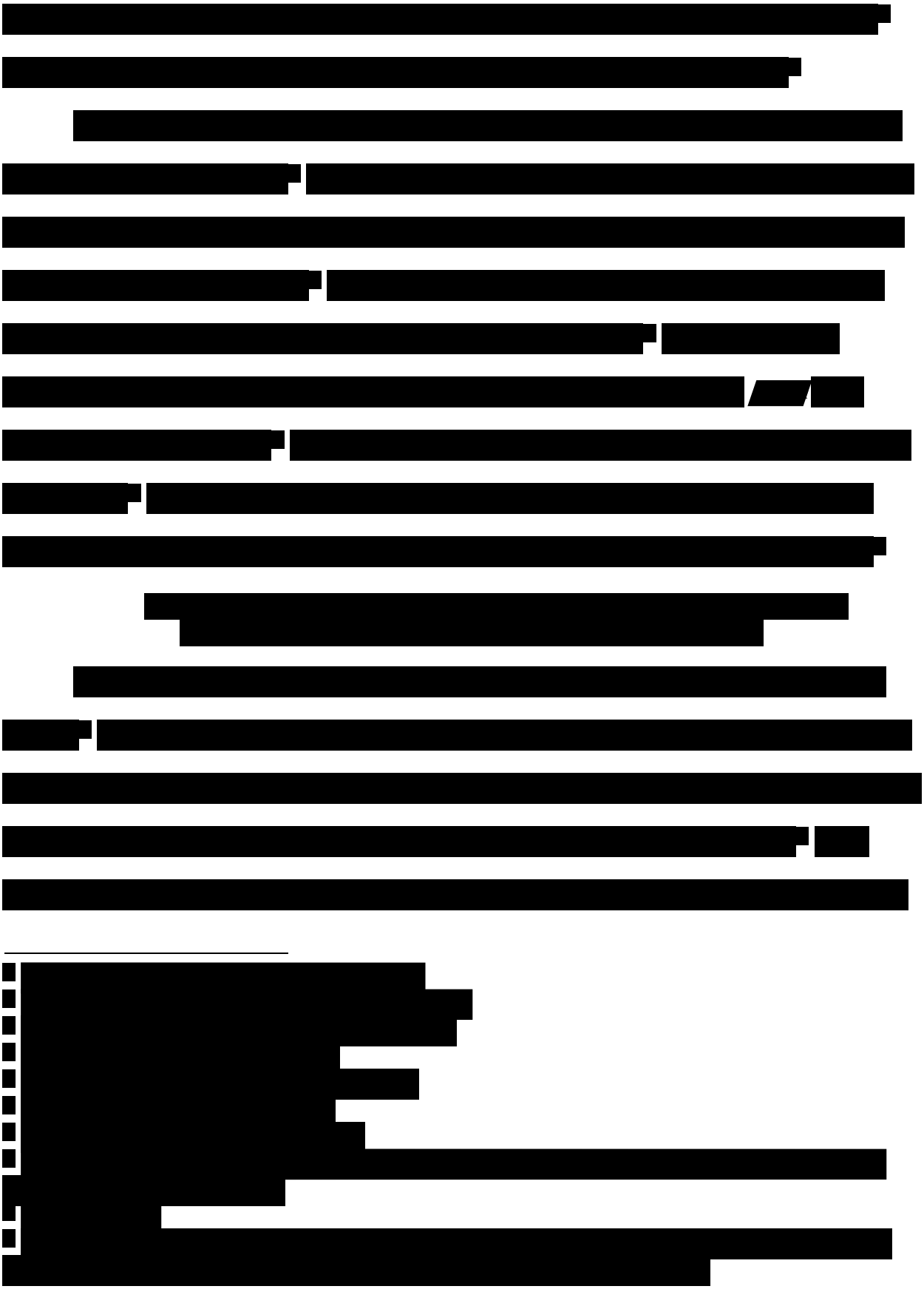
[78] [redacted]

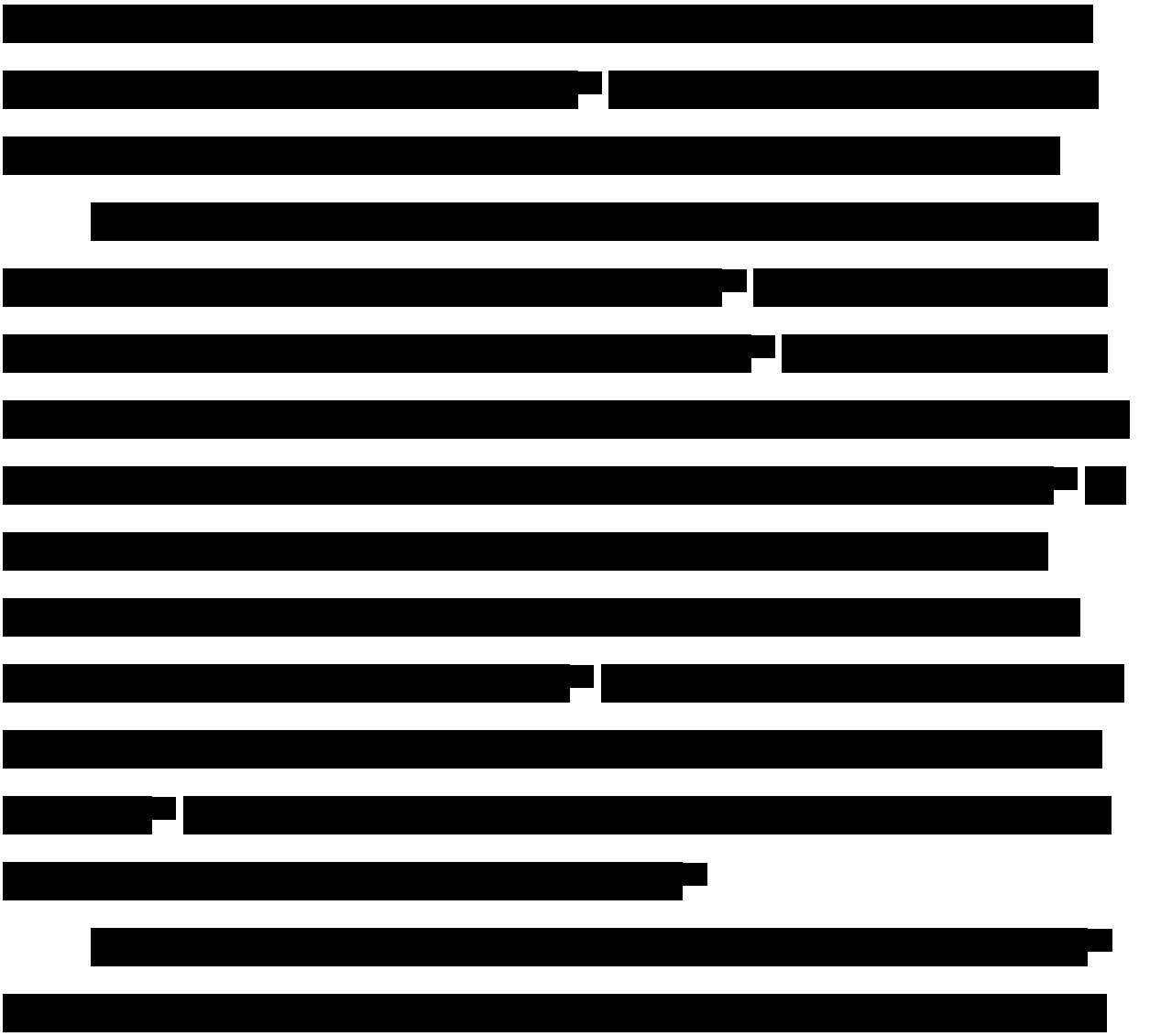
[79] *See* Expert Report of Luis A. Molina (Oct. 2, 2017) ("Molina Report") at ¶¶ 22-34.

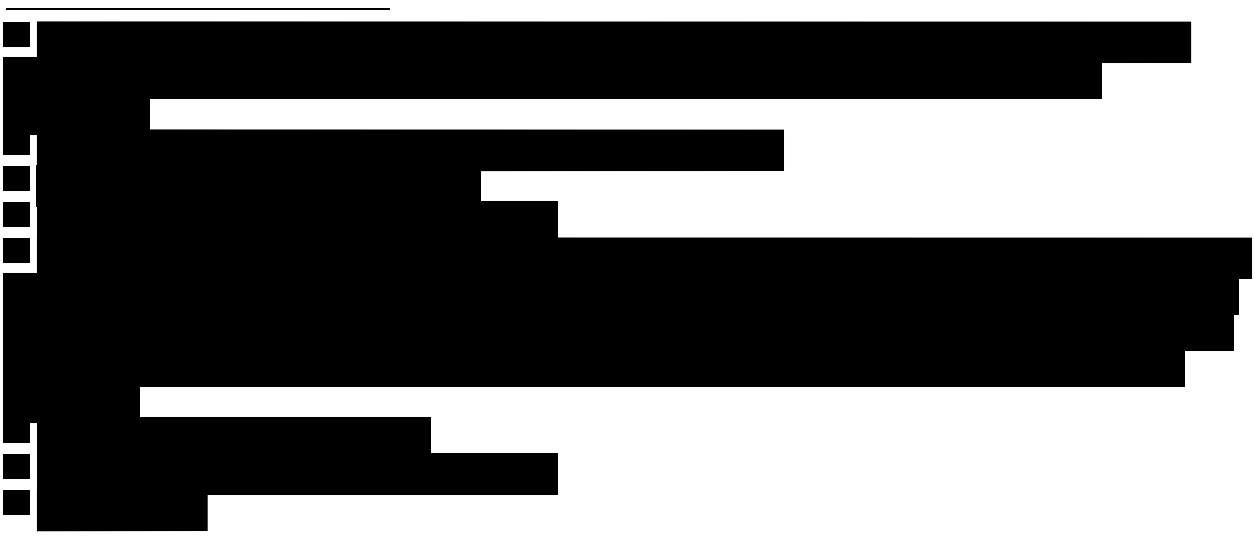
[redacted]

[82] Ex. 51, CELM-DANP-000017947; [redacted]

[83] *See* Appendix A, Tables 1 & 7.







D. CELGENE'S SHAM LITIGATION AGAINST WOULD-BE COMPETITORS

When Celgene's competitors manage to obtain sufficient samples of Thalomid or Revlimid from non-Celgene sources to demonstrate bioequivalence to the FDA, Celgene deploys its next stratagem: filing lawsuits and citizen petitions that further delay or prevent generic entry. This component of Celgene's anti-generic strategy involves the abuse of two interlocking regulatory requirements. The FDA regulations in force at the time that Celgene patented its REMS system permitted patent applicants to list their patents in the FDA's Orange Book as "drug substance (active ingredient) patents, drug product (formulation and composition) patents, [or] method-of-use patents." 21 C.F.R. § 314.53(b)(1). The FDA takes the patent-holder's classification of its patent at face value, announcing publicly that it "does not have the resources or the expertise to review patent information for its accuracy and relevance[.]"[116] Under the Hatch-Waxman Act, a patent-infringement lawsuit filed by the patent-holder against a manufacturer that has applied for FDA approval of a generic equivalent of the patented drug triggers a thirty-month "stay" in which the FDA cannot act on the generic manufacturer's application.[117]

Celgene's sham litigations involve exploiting both the new-drug listing regulations and the thirty-month stay provision of the Hatch-Waxman Act. The company's patents on its REMS system are transparently ***not*** "drug product (formulation and composition) patents." Rather than claiming the formulation or composition of a drug, every patent claims "*[m]ethod[] for delivering* a drug to a patient."[118] Nonetheless, Celgene abused the FDA's policy of not reviewing patentees' classifications by listing its REMS patents as "drug product" patents, meaning that Celgene would receive the automatic thirty-month stay after suing a would-be generic competitor. Because the patent-

[116] Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50338, 50343-45 (Oct. 3, 1994).
[117] 21 U.S.C. § 355(j)(5)(B)(iii).
[118] *See* Appendix B.

infringement lawsuit *also* prevents the FDA from approving any other generic-manufacturer's applications,[119] Celgene gains another *two-and-half years* of profitable monopoly simply by filing a lawsuit—even a baseless one.

> By providing pioneer drug manufacturers with the thirty month stay of ANDA approval for generic competitors, the [Hatch-Waxman Act] provides an opportunity for 'sham' or delaying litigation, because approval for the generic [drug application] cannot proceed while the patent litigation takes place. This litigation may have little to do with the underlying value of the patent(s) at issue, and [may amount] to a stipulated preliminary injunction without judicial review.[120]

As demonstrated below, Celgene is a practitioner *par excellence* of this tactic.

1. Celgene's Delay Tactics Prevent Lannett From Introducing a Thalidomide Generic for Over a Decade

As detailed in Appendix A, competitor Lannett offered to buy samples of Thalomid from Celgene [redacted]. Nonetheless, Celgene stalled for *four years* after learning that the FDA had approved Lannett's request to buy samples, [redacted]," and *two* rounds of consequent antitrust litigation.[121] These years of delay brought Celgene over [redacted] in revenue from its monopoly.[122]

[redacted]

[119] *See id.* § 21 U.S.C. § 355(j)(5)(B)(iv).
[120] Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 Berkeley Tech. L. J. 317, 327 (2002).
[121] Ex. 69, CELMN-FREJ-000155245; Ex. 70, CELM-FTCV-000006873; *see Lannett Co., Inc. v. Celgene Corp.*, No. 2:08-cv-0233 (E.D. Pa. Jan. 14, 2008); *Lannett Co., Inc. v. Celgene Corp.*, No. 2:08-cv-03920 (E.D. Pa. Aug. 15, 2008).
[122] *See* Ex. 56, CELMN-PASM-000001274 [redacted]
[123] Ex. 71, CELM-COUO-000020388.
[124] Ex. 72, CELMN-PASM-000037633.

[redacted][125] Because it had deceptively listed its distribution method REMS patents as drug product patents in the Orange Book, the mere filing of Celgene's lawsuit triggered a thirty-month stay that continues to keep generic thalidomide off the market, just as Celgene intended.[126] Meanwhile, the Classes continue to overpay.

2. Celgene Blocks Barr Through Bullying, Bribery, and Incessant Litigation

When Celgene learned in 2005 that competitor Barr Pharmaceuticals had obtained thalidomide samples from a [redacted],[127] Celgene's competition-suppression machine sprang into gear. [redacted][128] Not content with harassing Barr on its own, Celgene tried, unsuccessfully, to enlist the FDA in taking the drug from Barr.[129] While doing all within its power to squelch Barr's supply, Celgene moved to cut off an alternative source from French drug manufacturer Seratec. After learning that Seratec was poised to sell thalidomide to Barr, [redacted][130] [redacted].[132] [redacted]

[125] *Celgene Corp. v. Lannett Holdings, Inc.,* No. 2:15-cv-00697 (D.N.J. Jan. 30, 2015).
[126] *See* 21 U.S.C. § 355(j)(5)(B)(iii).
[127] *See* Ex. 73, CELM-ROTK-000001094.
[128] *Id.* at 1095.
[129] Ex. 74, CELM-ROTK-000001097.
[130] Ex. 75, CELM-FTCV-000004199; Ex. 76, CELM-FTCV-000001844.
[131] Ex. 76, CELM-FTCV-000001844.
[132] Ex. 77, CELM-FTCV-000000420.

[redacted]

Despite Celgene's success in eliminating Seratec as a potential supply source, Barr managed to collect enough ingredient to file an application for its thalidomide generic in 2006.[136] But Celgene was well-prepared for this eventuality. In its 2004 SEC filings, Celgene laid out its strategy to manipulate the Hatch-Waxman Act to its advantage, representing that it was "unlikely" that "generic competition" would "enter the market . . . before 2008" because

> challenges to Thalomid will require a generic competitor to make a patent certification of non-infringement and/or invalidity of our patents listed in the Orange Book . . . which would then, in turn, entitle us to up to a 30-month stay of market approval of that generic equivalent. By that time we plan to have at least partially replaced Thalomid sales with Revlimid sales.[137]

[redacted] Celgene had delayed Barr's application by fraudulently listing its

[133] Ex. 78, CELM-FTCV-000000840; Ex. 79, CELM-FTCV-000003556; Ex. 80, CELM-PASM-000037494.
[134] Ex. 80, CELM-PASM-000037494.
[redacted]
[136] Ex. 82, CELIUB-COUO-000739782.
[137] Ex. 83, CELM-COUO-000000380.
[138] Ex. 84, CELM-COUO-000009746, at 9747.

REMS patents as drug product patents in the FDA's Orange Book and filing its sham Citizen's Petition, and then it sued Barr for infringement, triggering the thirty-month stay of FDA action on Barr's application.[139] By the time the stay expired, the game was no longer worth the candle: just as Celgene had forecast in its 2004 SEC filing, the stay prevented Barr from entering until Revlimid's introduction forced Barr to "withdr[a]w the [FDA application] for lack of commercial visibility."[140]

3. Celgene Cedes [redacted] in Revenue to Natco to Delay Generic Entry

Finally, when it could not stop competitors from obtaining samples or FDA approval by any of its other anticompetitive gambits, Celgene eliminated competition through settlement terms that delayed generic entry and reduced generic penetration. One month after Natco notified Celgene that it had filed an application to market its generic equivalent of Revlimid,[141] Celgene sued for patent infringement.[142] The parties litigated to the eve of summary judgment before settling.[143] Under the key terms, Natco withdrew its FDA application and renounced future challenges to Celgene's patents.[144] Celgene dropped its lawsuit and gave Natco an exclusive license to sell generic Revlimid starting in 2022, subject to strict caps calculated as a percentage of Celgene's sales.[145] In effect, Celgene agreed to share its monopoly with Natco after 2022—valuable consideration worth approximately [redacted] of the reverse payment in *F.T.C. v. Actavis, Inc.*,[146] and vastly more than any costs Celgene avoided by settling. Industry analysts called the settlement a "win-win" for both parties,[147] but, they might have added, a loss for cancer patients and other end payors of Revlimid.

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[139] *See Celgene Corp. v. Barr Laboratories, Inc.*, No. 2:07-cv-00286 (D.N.J. Jan. 18, 2007).
[140] Ex. 85, CELMN-PASM-000005072, at 5074.
[141] Ex. 86, CELMN-FREJ-000074095.
[142] *Celgene Corp. v. Natco Pharma, Ltd.*, No. 2:10-cv-05197 (D.N.J. Oct. 8, 2010).
[143] *See* Order, *Celgene Corp. v. Natco Pharma, Ltd.*, No. 10-05197 (D.N.J. Dec. 15, 2015) (ECF No. 465).
[144] *See* Ex. 87, CELIUB-COUO-000000007, at 0009 (§ 5), 0036 (§1.17).
[145] *Id.* at 0034 (§1.11(d)).
[146] Leitzinger Report ¶ 91; Ex. 88, CELIUB-MYLA-000008236, at n.487, Ex. B1; *see F.T.C. v. Actavis, Inc.*, 133 S.Ct. 2223 (2013) (maximum value $342 million).
[147] Ex. 89, CELIUB-MYLA-000092165, at 2169.

III. ARGUMENT

A. GENERAL STANDARDS FOR APPLYING RULE 23

For a class to be certified, Plaintiffs must satisfy the requirements of Federal Rule of Civil Procedure 23(a) and 23(b)(3). The Rule 23(a) requirements are numerosity, commonality, typicality, adequacy of representation, and, implicitly, ascertainability. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613-14 (1997); *Baby Neal for and by Kanter v. Casey*, 43 F.3d 48, 55 (3d Cir. 1994). Under Rule 23(b)(3), certification is appropriate when: (i) common questions of law or fact predominate over questions affecting the individual class members only; and (ii) class treatment is superior to other available methods of adjudication.

To certify a class, the court must perform a "rigorous analysis" and "resolve all factual or legal disputes relevant to class certification." *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 215-16 (E.D. Pa. 2012) (citing *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 307, 320, 323 (3d Cir. 2008)).[148] This does not mean that the court must find that all merits questions will be resolved in favor of the class; class certification is appropriate when the class will prevail or fail in unison. *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 460, 465-66 (2013).

Courts have repeatedly found antitrust claims to be particularly well-suited for class actions. *See, e.g.*, *Gulf Oil Co. v. Bernard*, 452 U.S. 89, 99 (1981); *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 308-09 (3d Cir. 1998); *Eisenberg v. Gagnon*, 766 F.2d 770, 785 (3d Cir. 1985). More specifically, courts have repeatedly found antitrust cases challenging pharmaceutical companies' actions to delay the onset of generic entry to be suitable for class treatment for indirect purchasers or end payors. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 297 F.R.D. 168 (D. Mass. 2013), *aff'd* 777 F.3d 9 (1st Cir. 2015); *In re Flonase*, 284 F.R.D. 207; *Teva Pharm. USA, Inc. v. Abbott Labs.*, 252 F.R.D.

[148] "Factual determinations supporting Rule 23 findings must be made by a preponderance of the evidence." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 307.

213 (D. Del. 2008).[149]

Accordingly, the proposed Classes should be certified. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 910 (6th Cir. 2003) ("[c]onsumers of [a] patented drug . . . who allege that they were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand . . . . Preventing that kind of injury was undoubtedly a *raison d'etre* of the Sherman Act when it was enacted in 1890.").

B. CLASS CERTIFICATION IS APPROPRIATE UNDER RULE 23(A)

1. The Class Is So Numerous that Joinder Is Impracticable

Rule 23(a)(1) requires that a class be "so numerous that joinder of all members is impracticable." In the Third Circuit, when "the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 595 (3d Cir. 2012) (internal citation omitted). The class here consists of at least [redacted] of persons and entities that paid for some or all of the purchase price of Thalomid and Revlimid, as demonstrated by data obtained from subpoenas served on pharmacies.[150] Data that Dr. Leitzinger obtained from IMS demonstrates [redacted] Thalomid prescriptions and [redacted] Revlimid prescriptions purchased in the Antitrust/Consumer Protection Damages Class and Unjust Enrichment Damages Class states. Therefore, the numerosity requirement is easily satisfied here.

2. Plaintiffs Present Common Issues of Law and Fact

Rule 23(a) requires commonality among class members; that is, there must be questions of law or fact common to the class. "A putative class satisfies Rule 23(a)'s commonality requirement if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class." *In re Cmty. Bank of N. Va. Mortg. Lending Practices Litig.*, 795 F.3d 380, 408-09 (3d Cir. 2015) (internal

[149] *See also In re Lidoderm Antitrust Litig.*, 14-md-02521, 2017 WL 679367, at *27 (N.D. Cal. Feb. 21, 2017); *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672 (S.D. Fla. 2004); *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D. Mass. 2004); *In re Cardizen CD Antitrust Litig.*, 200 F.R.D. 326 (E.D. Mich. 2001).
[150] *See* Section III.B.5(1), *infra*; *see also* Leitzinger Report ¶ 46 (discussing data produced by pharmacies).

citation omitted), *cert. denied sub nom. PNC Bank v. Brian W.*, 136 S. Ct. 1167 (2016); *see also Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 359 (2011) ("We quite agree that for purposes of Rule 23(a)(2) '[e]ven a single [common] question' will do") (internal citation omitted).

In antitrust cases, the commonality requirement is often easily met. *See In re Neurontin Antitrust Litig.*, No. 02-1390, 2011 WL 286118, at *6 (D.N.J. Jan. 25, 2011) (commonality is "routinely found to be satisfied in antitrust cases alleging monopolization"); ABA Section of Antitrust Law, *Antitrust Law Developments* (7th ed. 2012), at 846 ("[c]ertification is rarely denied in antitrust actions for failure to meet the commonality requirement"); *see also Castro v. Sanofi Pasteur Inc.*, 134 F. Supp. 3d 820, 844 (D.N.J. 2015) (Arleo, J.) (finding commonality prong met due to "many common issues … including the relevant markets … Sanofi's willful maintenance and enhancement of monopoly power . . . whether Sanofi's conduct artificially inflated MCV4 prices, and damages.").

Indeed, whether Celgene engaged in anticompetitive conduct to impede competition for Thalomid and Revlimid is a question common to the class. Common questions include:

- Whether Celgene refused to sell samples of Thalomid or Revlimid to potential competitors to prevent generic entry;
- Whether Celgene blocked Barr from obtaining samples by entering into an exclusive supply contract with a foreign manufacturer of thalidomide;
- Whether Celgene improperly listed its "distribution method" patents in the Orange Book to exclude generic competitors;
- Whether Celgene filed a sham citizen petition and prosecuted sham patent litigation against competitors to prevent or delay generic entry;
- Whether Celgene's settlement and license agreement with Natco constitutes a large reverse payment in violation of the antitrust laws;
- Whether Celgene's conduct prevented generic competition (and thus lower prices) for Thalomid and Revlimid;
- When generic Thalomid and Revlimid would have been available for purchase in the United States, absent Celgene's conduct; and

- Whether Celgene had market power in the thalidomide and lenalidomide markets.

Each of these questions will be answered in the same way for every class member. *Wal-Mart*, 564 U.S. at 350 ("'What matters to class certification . . . [is] the capacity of a classwide proceeding to generate common *answers* apt to drive the resolution of the litigation.'") (internal citation omitted) (emphasis in original). As in *Flonase*:

> Although Indirect Purchasers assert state law claims of monopolization, UDTP, and unjust enrichment, proof of the essential elements of these claims will be common across the class and focused on GSK's behavior, not that of the individual class members. The common issues presented in each of the class members' claims include: (1) whether GSK unlawfully monopolized or attempted to monopolize the market for Flonase; (2) whether GSK unlawfully possessed and/or extended its monopoly power over the Flonase market; (3) whether GSK's actions caused the price of FP to be maintained at supra-competitive levels; (4) whether GSK's citizen petitions were intended to prevent generic entry and/or constitute unlawful conduct; (5) whether the class members suffered antitrust injury; and (6) whether GSK was unjustly enriched to the detriment of the class members. Resolving the allegations surrounding GSK's alleged conduct in delaying generic entry will resolve issues that are 'central to the validity of each one of the claims in one stroke.'

284 F.R.D. at 217 (citing *Wal-Mart*, 564 U.S. at 350). Similarly here, a jury could conclude that Celgene's conduct injured each proposed class member if it is established that Celgene's conduct increased prices above competitive levels. Plaintiffs have met the requirement of commonality.

3. Plaintiffs' Claims Are Typical of Those of the Classes

Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). "The named plaintiffs' claims are typical if they arise from the same alleged wrongful conduct and are based upon the same general legal theories." *Sanofi Pasteur*, 134 F. Supp. 3d at 844 (citing *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 532 (3d Cir. 2004)) (internal quotations omitted).

Claims need not be identical to be typical. *Sanofi Pasteur*, 134 F. Supp. 3d at 844 (citing *Baby Neal*, 43 F.3d at 57-58); *Eisenberg*, 766 F.2d at 786. "Indeed, even relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal

theories. . . . Where an action challenges a policy or practice, the named plaintiffs suffering one specific injury from the practice can represent a class suffering other injuries, so long as all the injuries are shown to result from the practice." *Baby Neal*, 43 F.3d at 58.

Plaintiffs allege that the same unlawful conduct, implemented by Celgene without reference to individual purchasers, injured all or virtually all class members. Each of the proposed class representatives paid for some or all of the purchase price of Thalomid or Revlimid, and each alleges that the price paid was supracompetitive, as a result of Celgene's conduct. This is sufficient to satisfy the typicality requirement. *See, e.g.*, *Marcus*, 687 F.3d at 599 ("When a class includes purchasers of a variety of different products, a named plaintiff that purchases only one type of product satisfies the typicality requirement if the alleged [misconduct] appl[ies] uniformly across the different product types.") (collecting cases); *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 171, 180 (E.D. Pa. 2015) ("[T]he different methods for purchasing and pricing the purchased eggs and egg products do not defeat typicality and adequacy, as the prices were all allegedly subjected, to and affected by, the antitrust conspiracy.").[151] Thus, Plaintiffs' claims regarding purchases of Thalomid or Revlimid are typical of the Classes.

4. Plaintiffs and Their Counsel Will Adequately Represent the Classes

Representative plaintiffs must "fairly and adequately protect the interests of the class." Fed. R.

[151] *See also In re Chocolate Confectionary Antitrust Litig.*, 289 F.R.D. 200, 217 (M.D. Pa. 2012) ("that customers paid different prices or purchased different brands of products does not defeat typicality… Relevant case law addresses the typicality requirement in terms of liability issues, not damages issues. All members of the putative class are direct purchasers of chocolate confectionary products . . . and allege that they made their purchases at supracompetitive prices.") (internal citations omitted); *In re Flat Glass Antitrust Litig.*, 191 F.R.D. 472, 480 (W.D. Pa. 1999) ("The overarching scheme is the linchpin of plaintiffs' amended complaint, regardless of the product purchased, the market involved or the price ultimately paid. Furthermore, the various products purchased and the different amount of damage sustained by individual plaintiffs do not negate a finding of typicality, provided the cause of those injuries arises from a common wrong."); ALBA CONTE & HERBERT B. NEWBERG, NEWBERG ON CLASS ACTIONS § 3:35 (5th ed. 2012) ("Newberg") ("the proposed class representative's claims are generally held to be typical of the class members' claims even if there are variations in the manner in which members of the class purchased from the defendant, variations in the kind of product purchased, differences in price . . . .").

Civ. P. 23(a)(4). The "inquiry under Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent." *Amchem*, 521 U.S. at 625. The adequacy determination "depends on two factors: (a) the plaintiff's attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (b) the plaintiff must not have interests antagonistic to those of the class." *In re Flonase*, 284 F.R.D. at 218 (quoting *New Directions Treatment Servs. v. City of Reading*, 490 F.3d 293, 313 (3d Cir. 2007)).[152] Both requirements are satisfied here.

There are no actual or potential conflicts of interest between the representative Plaintiffs and members of the proposed Classes. Plaintiffs and each class member paid more for thalidomide or lenalidomide than they would have absent Celgene's conduct. As indirect purchasers, Plaintiffs have standing to bring this action for injunctive relief under Section 16 of the Clayton Act and for damages under the laws of California, the District of Columbia, Florida, Kansas, Maine, Massachusetts, Michigan, Nebraska, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, and Tennessee. *See, e.g.*, *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205, 213 (E.D. Pa. 2009) (adopting "the view that a plan's claim arises where the overcharge occurs, and recogniz[ing] that each plan may have a cause of action in multiple states"); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 533 (E.D. Pa. 2010) (finding plaintiff health and welfare plans had "standing to bring a claim under the laws of the states where they are located, and where they purchased Flonase or reimbursed their members for Flonase purchases").[153] Thus, as this Court recognized in ruling on

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[152] Only "fundamental" conflicts relating to an "issue at the very heart of the suit" prevent a plaintiff from meeting the adequacy requirement. *In re Ins. Brokerage Antitrust Litig.*, No. 04-5184, 2007 WL 2589950, at *11 (D.N.J. Sept. 4, 2007) (internal citation omitted), *aff'd*, 579 F.3d 241 (3d Cir. 2009). In fact, "[a]dequacy does not require complete identity of claims or interests between the proposed representative and the class. All that is required—as the phrase 'absence of conflict' suggests—is sufficient similarity of interest such that there is no affirmative antagonism between the representative and the class." Newberg, at § 3:58.

[153] *See also In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 151 (E.D. Pa. 2009) (concluding "that the plaintiff benefit funds may bring claims under the laws of the states in which they are located and in which their members, for whom they have reimbursed purchases of Wellbutrin XL, reside"); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1080 (N.D. Cal. 2014) ("The EPPs do not need to reside in a particular state to have

Celgene's Motion to Dismiss, Plaintiffs have standing to adequately represent the class. *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2015 WL 9589217, at *18 (D.N.J. Oct. 29, 2015) ("The Court finds that the factual allegations [that Plaintiffs are located in certain states and paid and/or reimbursed their members for the price of Thalomid and Revlimid in other states] support plaintiffs' standing to pursue state law claims.").

All Plaintiffs share an interest in establishing Celgene's liability and in obtaining the largest monetary recovery possible. The basis of each class member's claim against Celgene is the same—that Celgene's scheme to exclude competition caused every class member to pay more for thalidomide or lenalidomide than they would have if Celgene had not blocked generic competition. *See Sanofi Pasteur*, 134 F. Supp. 3d at 844-45 ("Each of the named plaintiffs has the same interest as the class members in establishing that (a) the scheme occurred, (b) it violated the antitrust laws, and (c) it resulted in artificially inflated Menactra prices."). Therefore, Celgene's actions injured the class representatives and the absent class members in the same manner for which identical relief is sought. Accordingly, the interests of the named Plaintiffs and the proposed class members align.

In appointing Interim Co-Lead Counsel, the Court has already recognized that the firms of Hausfeld LLP, Block & Leviton LLP, and Hach Rose Schirripa & Cheverie LLP, met the requirements of Rule 23(g). ECF No. 92. Interim Co-Lead Counsel are qualified, experienced, and thoroughly familiar with antitrust class action litigation. They have spent considerable time and resources on this litigation, including engaging in discovery and working with experts. They have extensive knowledge of substantive and class action law, as well as complex litigation rules, practice, and procedure. Thus, the requirements of Rule 23(a)(4) are satisfied.

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standing to assert claims under that state's laws. The question is whether the EPP was harmed in a particular state by either its own purchase of a Lidoderm or generic patch or by its reimbursement of a purchase of a Lidoderm or generic patch in that state.").

5. Membership in the Proposed Class is Ascertainable

A class must be ascertainable to be certified in the Third Circuit. *See, e.g., Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015). A Rule 23(b)(3) class must be (1) defined with reference to objective criteria, and (2) there must be a "reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition." *Id.* (internal citation omitted). This "ascertainability" inquiry "does not mean that a plaintiff must be able to identify all class members at certification[.]" *Id.* "Plaintiff[s] need not, at the class certification stage, demonstrate that a single record, or set of records, conclusively establishes class membership." *City Select Auto Sales Inc. v. BMW Bank of N. Am., Inc.*, 867 F.3d 434, 441 (3d Cir. 2017). Instead, a plaintiff need only show that "'class members *can* be identified.'" *Byrd*, 784 F.3d at 163 (emphasis in original) (quoting *Carrera v. Bayer Corp.*, 727 F.3d 300, 308 n.2 (3d Cir. 2013)).

Here, the proposed Classes are defined with reference to objective criteria. Any person or entity that paid some or all of the purchase price of thalidomide in any form after November 6, 2010 or lenalidomide in any form after January 29, 2011 for their personal consumption or the consumption of their members or subscribers is a member of the Classes (unless they fall within one of the named exclusions). *See Lidoderm*, 2017 WL 679367, at *25 (similar class definition found to be based on sufficiently objective criteria); *Qureshi v. OPS 9, LLC*, No. 14-1806, 2016 WL 6434345, *2 (D.N.J. Oct. 28, 2016) (Arleo, J.) (ascertainability requirement met when name of account holder, nature of check, and identity of the entity receiving the check provide sufficient evidence that debt is "consumer debt" under the Fair Debt Collection Practices Act).

The Classes consist of patients, health benefit plans, and insurers that paid some or all of the price of Thalomid or Revlimid. Administratively feasible methods exist to identify them.

a. Administratively Feasible Methods Exist to Identify Class Members

The vast majority [redacted] of class payments imposed by Celgene's scheme were suffered by

third-party payors (TPPs) consisting of health benefit plans and insurers.[154] TPPs may demonstrate membership in the Classes by submitting claims records of their members'/insureds' claims for purchases of Thalomid and Revlimid. For example, every named Plaintiff maintains records of claims for its drug purchases, and insurance companies maintain claims records in the ordinary course of business.[155] Plaintiffs also have transaction data from 24 pharmacies that dispensed Thalomid and Revlimid during the Class Period, about half of the total volume shipped by Celgene.[156] These data usually contain a field identifying the TPP, which can be used to confirm a TPP's purchase.[157]

Patients that suffered overcharges either because they were uninsured and bore the full cost of Thalomid or Revlimid, or because their co-pays would have been lower with a generic, are also readily identifiable by several methods. *First*, as part of its REMS programs, Celgene requires every patient that receives Thalomid or Revlimid "to register within a single database environment that is maintained by Celgene."[158] The database contains the last name, date of birth, partial social security number, prescribing physician, and dispensing pharmacy for each patient, and the name and address of every pharmacy dispensing either drug.[159] Thus, every patient that has received either drug can be identified using Celgene's own data. *See City Select*, 2017 WL 3496532, at *8 n.4 (vacating denial of certification where class could be ascertained through defendant's database, supplemented by class member affidavits); *Byrd*, 784 F.3d at 169 (reversing denial of certification where "[the defendant's] own records reveal" one group of class members, and other records could be used to identify others).

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[154] *See* Leitzinger Report ¶ 37.

[155] *See, e.g.*, Ex. 90, ThalRev_Providence_000133; Ex. 91, Thal_IUOE_00001-07; Ex. 92, ThalRev_IUB_000622.

[156] Leitzinger Report ¶ 46.

[redacted]

[159] Ex. 30, CELM-NDAT-000023723, at 3740, 3920-3921 (Pharmacy Registration); *see id.* at CELM-NDAT-000023929 (Patient Registration).

Even without Celgene's REMS data, patients can be identified through any one of three discrete types of records in their possession. *First,* patients may retain receipts of their drug-purchases.[160] Given the staggering cost of Thalomid and Revlimid and the availability of tax deductions for prescription drug purchases,[161] patients are more likely to retain receipts for Thalomid and Revlimid than for ordinary consumer purchases. *Second,* even patients who do *not* keep receipts can prove their purchase of either drug by obtaining records of their drug purchases from the dispensing pharmacy.[162] *Third*, a patient who has neither retained purchase receipts nor requested records from her pharmacy could demonstrate her purchase by obtaining claims records from her insurer.[163] Any one of these documents in patients' possession would suffice to demonstrate their purchase of Thalomid or Revlimid. *See Byrd*, 784 F. 3d at 170.

b. The Exclusions Present No Barrier to Ascertainability

The exclusions of "single flat co-pay consumers" and "fully insured health plan[s]" pose no barrier to ascertainability. Both exclusions are rare: in any given year during the Class Period, only 5-7% of workers that received health insurance through their employer participated in plans that featured a single flat co-pay.[164] Similarly, nearly two-thirds of workers that receive health benefits through their employer are covered by a self-insured (i.e., not fully-insured) benefit plan. *Id.* at 188. Nonetheless, the application of either exclusion to a prospective class member can be determined based on any one of several documents in the possession of patients and plans. *See* Appendix D.

Whether a patient's Thalomid or Revlimid purchase was subject to a "single flat co-pay" can

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[160] *E.g.*, Ex. 95, ThalRev_Mitchell_000053.
[161] *See* IRS Publication 502 (2016), *available at* https://www.irs.gov/publications/p502/ar02.html
[162] *E.g.*, Ex. 96, ThalRev_OC_0000001.
[163] *See, e.g.*, Blue Shield of California, Members, Claims, *available at* https://www.blueshieldca.com/bsca/bsc/poc/member?uri=login:login&originPage=/bsca/bsc/mysite/member/mp/claimssummary (last accessed September 8, 2017) (insurance company website providing access to individual members' claims history).
[164] *See* The Henry J. Kaiser Family Foundation, 2016 Employer Health Benefits Survey Ex. 9.2 (Sept. 14, 2016), *available at* http://www.kff.org/health-costs/report/2016-employer-health-benefits-survey/.

be verified by comparing the amount and date of the drug purchases listed on her purchase receipt, *e.g.*,. Ex. 95, ThalRev_Mitchell_000053, or the pharmacy- or insurer-supplied prescription history, *e.g.*, Ex. 96, ThalRev_OC_0000001, with the description of the prescription drug benefit provided by her health benefit plan or insurer. Federal law requires non-governmental employee benefit plans to give participants and their beneficiaries a "Summary Plan Description" (SPD). *See* 29 U.S.C. § 1022 (SPD requirement). The SPD must "include a description of: any cost-sharing provisions, including premiums, deductibles, coinsurance, and copayment amounts for which the participant or beneficiary will be responsible," 29 C.F.R. § 2520.102-3(j)(3), and must be "written in a manner calculated to be understood by the average plan participant." 29 U.S.C. § 1022(a). Similarly, government-sponsored prescription drug benefit plans provide plan benefit statements to covered employees and their beneficiaries. See Appendix C. Unsurprisingly in light of these consistent requirements, every third party payor class representative provided to its participants and beneficiaries in its prescription drug program, and plaintiff David Mitchell received from his employer, a summary document stating in plain English that brand and generic drugs are subject to different co-pay amounts.[165]

Similarly, whether a TPP is a "fully insured health plan," Amended Compl. ¶ 263, can be ascertained based on any one of several documents in the possession of the plans themselves:

- A plan may demonstrate that it is not fully insured by submitting a copy of its SPD, which must specifically "identify any insurance company . . . through which the plan is funded or benefits are provided" and "whether and to what extent benefits under the plan are guaranteed under a contract or policy of insurance issued by the issuer." 29 C.F.R. § 2520.102-3(q).[166]

- The prescription drug program contracts between self-insured plans and outside benefit managers include a clause requiring the plan to reimburse the manager for prescription drug benefit claims submitted by plan participants.[167] These payment arrangements demonstrate that the plans themselves—not an insurer—pay the cost of members'

[165] *See, e.g.*, Ex. 97, ThalRev_Mitchell_000001, at 0025; Ex. 98, Thal_IUOE_000008, at 0061; Ex. 99, ThalRev_Providence_000879.
[166] *See, e.g.* Ex. 98, Thal_IUOE_000008, at 0089 (Plaintiff IUOE's SPD disclosing its funding mechanism).
[167] *E.g.*, Ex. 100, ThalRev_Providence_000001, at 0011; Ex. 101, ThalRev_DEA_03715.

prescription drug claims.[168]

- Municipalities and other government entities that issue revenue bonds disclose the funding arrangements for their employee benefit plans in the public financial statements accompanying their bond offerings.[169]

All three types of documents are in the possession of the plan and can be submitted to demonstrate that it is not "fully insured." Using these documents to confirm class membership is fully consistent with the Third Circuit's requirements, indeed, "[t]here will always be some level of inquiry required to verify that a person is a member of a class. . . . Such a process of identification does not require a 'mini-trial,' nor does it amount to 'individualized fact-finding,' and indeed must be done in most successful class actions." *Byrd*, 784 F.3d at 170-71 (quoting *Carrera*, 727 F.3d at 307). Indisputably, "'class members *can* be identified.'" *Id.* at 163 (quoting *Carrera*, 727 F.3d at 308 n.2).

C. CLASS CERTIFICATION IS APPROPRIATE UNDER RULE 23(B)(3)

Class certification is appropriate under Rule 23(b)(3) if "questions of law or fact common to class members predominate over any questions affecting only individual members," and if "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy."

1. Common Issues Predominate Across Plaintiffs' Antitrust Claims

To satisfy the predominance inquiry of Rule 23(b)(3), Plaintiffs must make a "showing that *questions* common to the class" predominate—not that every element of a claim is susceptible to classwide proof, and "not that those questions will be answered, on the merits, in favor of the class." *Amgen*, 568 U.S. at 459 (emphasis in original); *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 756 (3d Cir. 1974); *McClendon v. Cont'l Grp., Inc.*, 113 F.R.D. 39, 43 (D.N.J. 1986).[170]

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[168] *See* Ex. 101, ThalRev_DEA_03715, at ¶ 4.2(a)(ii) (providing for direct invoicing for covered drug claims to the plan); Ex. 100, ThalRev_Providence_000001, at ¶ 7 (same).
[169] *E.g.* Ex. 102, ThalRev_Providence_000664 at 0715 (City of Providence financial statement disclosing that its health benefit plan is self-insured).
[170] In the Third Circuit, this question is often considered in conjunction with the test for commonality under Rule 23(a)(2). *Georgine v. Amchem Prods., Inc.,* 83 F.3d 610, 626 (3d Cir. 1996), *decl. sub nom. Amchem Prods. Inc. v. Windsor,* 521 U.S. 591 (1997).

At its core, the predominance inquiry "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation" and "assesses whether a class action 'would achieve economies of time, effort, and expense, and promote uniformity of decision as to persons similarly situated.'" *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 297 (3d Cir. 2011).

Common issues predominate when—as here—liability depends on the defendant's conduct. *See Sullivan*, 667 F.3d at 299 (*comparing In re Warfarin Sodium Antitrust Litig.*, 391 F.3d at 528 (liability dependent on defendant's conduct) *with In re LifeUSA Holding Inc.*, 242 F.3d 136, 145-46 (3d Cir. 2001) (reversing certification of litigation class where plaintiffs' claims arose not out of one single event or misrepresentation but out of non-standardized and individualized sales pitches)). For this reason, the predominance requirement "is a test readily met in certain cases alleging consumer or securities fraud or violations of the antitrust laws." *Amchem*, 521 U.S. at 625; *In re Neurontin*, 2011 WL 286118, at *6 ("Courts have routinely found that proof of [monopolization] focuses on the defendant's conduct, not on the conduct of individual class members, and is therefore well suited for class treatment."); *Weisfeld v. Sun Chem. Corp.*, 210 F.R.D. 136, 141 (D.N.J. 2002), *aff'd*, 84 F. App'x 257 (3d Cir. 2004) ("To ascertain whether there has been a violation of the antitrust laws, a court will have to examine Defendants' conduct, and will not consider the conduct of individual class members.") This is also true when plaintiffs bring their claims for monopolization under state law. *Sullivan*, 667 F.3d at 285 (affirming the certification of a nationwide class of indirect purchasers based on a "straightforward application of Rule 23 and our precedent"); *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d at 528 (indicating that allegations of conduct "in violation of federal and state consumer fraud and antitrust laws . . . naturally raise several questions of law and fact common to the entire class and which predominate over any issues related to individual class members").

In this case, common issues predominate because "[v]irtually all significant questions… will turn on Defendant's conduct, not on individual plaintiffs'." *Sanofi Pasteur*, 134 F. Supp. 3d at 845.

a. Common Proof of Celgene's Monopoly Power and Exclusionary Conduct in Violation of State Competition Laws Predominates

Plaintiffs' antitrust claims are readily susceptible to common proof. At this stage, Plaintiffs only need to make a threshold showing that the essential elements of their claims can be proven at trial with common evidence. *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 489 (3d Cir. 2015) ("The question is not what valid claims can plaintiffs assert; rather, it is simply whether common issues of fact or law predominate."). Here, Plaintiffs' monopolization and attempted monopolization claims demonstrate that common questions predominate over individualized issues.

A federal or state antitrust monopolization claim generally has the following elements: (1) the possession of monopoly power in the relevant market; and (2) the willful acquisition or maintenance of that power by anticompetitive or exclusionary means. *See Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 480 (1992); *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 137 (E.D. Pa. 2011) ("The antitrust laws and consumer protection laws for [California, Florida, Nevada, New York, Tennessee, and Wisconsin] do not differ in material respects."); *see also* Appendix E (showing state law elements of antitrust claims). Similarly, in order to sustain an attempted monopolization claim, a plaintiff must show: "(1) that the defendant has engaged in … anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 317 (3d Cir. 2007) (internal citation omitted); Appendix E.

The Supreme Court has defined monopoly power as "the power to control prices or exclude competition." *Grinnell*, 384 U.S. at 571 (internal citation omitted). Proof of Celgene's market power involves an analysis of common evidence, including market data, Dr. Leitzinger's expert analysis,[171]

[171] *See* Leitzinger Report at ¶ 10(d) ("The economic issues associated with relevant antitrust market definition and monopoly power--i.e., the competitive interactions between Thalomid, Revlimid, AB-rated generic versions of those drugs and other drugs in the same therapeutic categories; the impact of other drug alternatives, including generics, on prices and sales of Thalomid and Revlimid; and, the likely effects on Celgene's pricing power . . . will be the same as to each member of the Classes. Hence, the economic proof associated with these issues will be common to members of the proposed Classes.").

and economic theory, which apply to Plaintiffs' claims on a classwide basis. *See*, *e.g.*, *In re Wellbutrin*, 282 F.R.D. at 140 ("The issues of relevant market [and] monopoly power . . . can be proven using common, class-wide evidence."); *Teva Pharm.*, 252 F.R.D. at 228 ("the court finds that each putative class member, had they pursued their claims individually, would have been required to prove identical facts, such as defendants' monopoly power."); *Stephenson v. Bell Atl. Corp.*, 177 F.R.D. 279, 287 (D.N.J. 1997) (listing monopoly power as a common question). Specifically here, as Dr. Leitzinger explains, Plaintiffs can establish Celgene's market power directly through its supracompetitive pricing and high profit margins or circumstantially based on its dominant share of the relevant markets—evidence that is common to every class member. Leitzinger Report at ¶¶ 72–79, 84, 88, 92–93.

Celgene's monopoly power can also be demonstrated through circumstantial evidence. *See United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005). Dr. Leitzinger demonstrates how the relevant market can be defined using DOJ/FTC Merger Guidelines as a roadmap. Leitzinger Report at ¶¶ 87-88. Market definition is a common question. *See Sanofi Pasteur Inc.*, 134 F. Supp. 3d at 846 ("Defining the relevant market focuses on common data, expert analysis, and economic tests; such proof generally does not vary by class member."); *Teva Pharm.*, 252 F.R.D. at 225 (listing market definition as a common question because it focuses on defendant's conduct); *Stephenson*, 177 F.R.D. at 286-87 (stating, "There can be no doubt that plaintiffs' antitrust claims present numerous common questions of both law and fact requiring the court's adjudication," including, "the definition of the relevant geographic and product markets").

Finally, Plaintiffs must show that Celgene maintained its monopoly power in the market through "exclusionary conduct." *Eastman Kodak Co.*, 504 U.S. at 488. A defendant engages in exclusionary conduct when its actions make "a significant contribution to maintaining monopoly power" that results in harm to competition, without a legitimate business justification. *Dentsply*, 399 F.3d at 187. Where the proffered justifications are found to be pretextual, the conduct may be found

to be exclusionary. *Eastman Kodak*, 504 U.S. at 484. In conducting the exclusionary conduct analysis, courts "look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003).

Here, Plaintiffs will show through common evidence that Celgene engaged in exclusionary conduct that harmed competition by preventing generic entry. *See Am. Sales Co. v. SmithKline Beecham Corp.*, 274 F.R.D. 127, 135 (E.D. Pa. 2010) (holding proof of defendant's anticompetitive strategy and intent to delay generic market entry satisfied the predominance inquiry); *Teva Pharm.*, 252 F.R.D. at 225 (finding "whether defendants maintained monopoly power by delaying generic entry" to be a common issue); *In re Wellbutrin Sr Direct Purchaser Antitrust Litig.*, No. 04-5525, 2008 WL 1946848, at *9 n. 21 (E.D. Pa. May 2, 2008) (collecting cases, noting, "This finding of predominance is consistent with the findings of other courts in which plaintiffs have alleged antitrust injuries resulting from the delayed entry of generic drug competitors"); *In re Relafen Antitrust Litig.*, 218 F.R.D. 337, 343 (D. Mass. 2003) (finding the predominance requirement satisfied when defendant prosecuted "sham patent lawsuits" to delay generic market entry, where plaintiffs intended to prove their claims using "generalized evidence and methodologies," including government studies, defendant's internal projections and documents, and price and sales data).[172] Here, Celgene's actions were not differentiated with respect to individual purchasers; the focus is squarely on Celgene. Moreover, the absence of any pro-competitive business justification for Celgene's conduct will be proven by common evidence. Thus, common issues predominate as to Celgene's violation of federal and state antitrust laws.

[172] *See also In re Modafinil Antitrust Litig.*, 837 F.3d 238, 266 (3d Cir. 2016), *as amended* (Sept. 29, 2016) (holding that common proof whether settlements between brand name and generic manufacturers were anticompetitive reverse payments to delay generic market entry met the predominance requirement of class certification) (denying class certification on other grounds); *In re K-Dur Antitrust Litig.*, No. 01-1652, 2008 WL 2699390, at *4 (D.N.J. Apr. 14, 2008), *subsequently aff'd*, 686 F.3d 197 (3d Cir. 2012) (judgment vacated, then reinstated following *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013)) (finding that whether defendant entered into illegal reverse payment settlement agreements presented common questions).

b. Proof of Celgene's Unjust Enrichment is Common to the Class

Plaintiffs' unjust enrichment claims are well-suited for class treatment. It is a universally accepted legal principle that "[a] person who is unjustly enriched at the expense of another is liable in restitution to the other." RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 1 (2001). The standard prima facie elements of unjust enrichment are: (1) a benefit conferred by a plaintiff upon defendant; (2) knowledge by the defendant of the benefit; and (3) retention of the benefit by defendant under circumstances where it would be unjust to do so without payment. *See*, *e.g.*, *In re Liquid Aluminum Sulfate Antitrust Litig.*, No. 16-md-2687, 2017 WL 3131977, at *29 (D.N.J. July 20, 2017); *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 544 (D.N.J. 2004).[173]

Here, Celgene's illegal conduct excluded generic competitors from the market; such a delay in generic competition enriched Celgene at the expense of Plaintiffs; and, as a matter of equity, Celgene should be required to return its excess profits. Plaintiffs will prove these allegations with class-wide evidence. Celgene's excess profits can be demonstrated with market-wide evidence, including total sales volumes and average prices as a result of Celgene's conduct, in comparison to outcomes absent that conduct, factoring in incremental costs that Celgene faces in connection with increased sales.174

[173] The legal standard for unjust enrichment is consistent throughout the relevant jurisdictions. *See* Appendix E (listing unjust enrichment elements in relevant states); *Liquid Aluminum*, 2017 WL 3131977, at *29 n.27 ("The Court notes that there are no material differences between jurisdictions regarding the law of unjust enrichment.") *citing In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 58 (D.N.J. 2009), *modified on other grounds*, 2010 WL 2976496 (D.N.J. July 22, 2010) ("While there are minor variations in the elements of unjust enrichment under the laws of the various states, those differences are not material and do not create an actual conflict."); *In re Terazosin*, 220 F.R.D. at 697 n.40 (same). *See also* Daniel R. Karon, *Undoing the Otherwise Perfect Crime - Applying Unjust Enrichment to Consumer Price-Fixing Claims*, 108 W. Va. L. Rev. 395, 410 & n.79 (2005) (emphasizing that all states' unjust-enrichment laws "contain virtually identical elements" and listing the elements and seminal case by state).

[174] *See* Leitzinger Report at ¶ 10(c) ("Celgene's unjust enrichment [is] readily susceptible to formulaic calculation and will not require individualized inquiries regarding members of the Classes."). *See*, *e.g.*, Ex. 56, CELMN-PASM-000001274.

c. Plaintiffs Will Use Common Methodologies to Prove Impact on the Classes Caused by Celgene's Conduct

Antitrust impact is shown where class members suffered . . . payment of an overcharge on at least one transaction." *See Sanofi Pasteur*, 134 F. Supp. 3d. at 847 (citing *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114 n.9 (1969); *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 151 (3d Cir. 2002)). Through Dr. Leitzinger's analysis, plaintiffs can demonstrate that (1) Celgene's conduct effectively kept the price of thalidomide and lenalidomide higher than it would have been in a competitive market, and (2) all or substantially all class members paid these inflated prices. *See Sanofi Pasteur*, 134 F. Supp. 3d. at 847 (approving two-step method of proving impact by first showing that defendant's conduct increased prices, and then that substantially all class members paid those inflated prices) (citing *In re Linerboard*, 305 F.3d at 153-55).

Plaintiffs propose to show antitrust impact and injury by common proof that: (i) generic drugs are significantly less expensive than the branded version of the same drug; (ii) purchasers pay significantly less for generic drugs than they do for branded drugs; (iii) the presence of a second generic drug product on the market further drives down generic drug prices; (iv) state laws and health benefit plans promote or require the substitution of less expensive generic drugs for branded versions once the generic drug products are on the market; (v) Celgene's conduct delayed the availability of, and competition from, thalidomide and lenalidomide; and (vi) Celgene's conduct impacted all or nearly all members of the Classes. *See* Leitzinger Report ¶¶ 16-37; Molina Report ¶¶ 35-54.

The industry reports and academic studies on which Dr. Leitzinger relies[175] in concluding that generic entry results in lower prices for end-payors are the type of evidence of impact that has been generally accepted by courts in similar cases of generic exclusion. *See, e.g., Lidoderm*, 2017 WL 679367, at *10 (accepting as common evidence of classwide impact Dr. Leitzinger's testimony and citations to

[175] *See* Leitzinger Report § IV(A) "Economic Literature Pertaining to the Effects of Generic Competition."

academic and industry studies explaining that the introduction of generic drugs creates significant cost savings for consumers); *In re Flonase Antitrust Litig.*, 284 F.R.D. at 221 (accepting as classwide proof of impact historical data and academic studies detailing how the price of generic drugs decline upon market entry and with multiple entrants).

Similarly, end-payors (and all or virtually all class members) benefit from less expensive bioequivalent generic drugs, due to state laws and health benefit plan policies which promote or require the substitution of less expensive, bioequivalent generic drugs for branded drugs. *See, e.g.*, Cal. Bus. & Prof. Code § 4073(a) (permitting a pharmacist to fill a prescription for a brand name product with its generic alternative); N.Y. Educ. §6810(6)(a) (requiring generic substitution unless the prescriber specifically indicates to dispense as written); Leitzinger Report ¶ 14.[176]

Dr. Leitzinger reviewed this evidence, as well as [redacted] data on benchmark drugs, and actual prices paid by class members through a wide sampling of data from pharmacies dispensing the drugs – all evidence common to the Classes. He concludes that "evidence that is common to members of the proposed Classes shows that the absence of generic alternatives for Revlimid and Thalomid to date has likely caused [redacted] (or more) of the proposed Class members, collectively accounting for over [redacted] of the payments for these drugs within each Class, to incur at least some overcharge in the amounts they paid to buy Thalomid and Revlimid."[177]

[176] For example, Providence's plan members substituted generic drugs for branded drugs 93-99.9% of the time during the class period, and both Providence and Local 39 encouraged generic substitution by requiring their members to pay some or all of the difference in price between the brand name drug and the generic. *See* Ex. 103, ThalRev_Providence_005055, at 05058; Ex. 104, ThalRev_Providence_001169; Ex. 105, ThalRev_Providence_004872, at 4873; Ex. 98, THAL_IOUE_00008, at 0061; Ex. 106, ThalRev_Providence_002096, at 2100; Ex. 107, ThalRev_Providence_001172, at 1174; Ex. 108, ThalRev_IUB_000544.

[177] Leitzinger Report at ¶ 10(b).

d. The Formulaic Measure of the Class's Damages is a Predominating Common Question and Classwide Methodologies Are Available to Calculate Damages

Common issues also predominate "as to the element of 'measureable damages' on a classwide basis." *See In re Processed Egg Products*, 312 F.R.D. at 202 (citing *Hydrogen Peroxide*, 552 F.3d at 311-12). "At the class certification stage, the plaintiffs are not required to prove damages by calculating specific damages figures for each member of the class, but rather they must show that a reliable method is available to prove damages on a class-wide basis." *Id.* (citing *In re Wellbutrin*, 282 F.R.D. at 144 ("Circuit courts have largely rejected the interpretation urged by Defendants—that variations in damages calculations between and among class members defeat predominance.") (collecting cases)). Thus, at the class certification stage, damages are typically calculated on an aggregate basis. *See King Drug Co. v. Cephalon, Inc.*, 309 F.R.D. 195, 212 (E.D. Pa. 2015) ("Courts have held that proof of aggregate damages is appropriate in class actions."); *Byrd*, 784 F.3d at 176 (Rendell, J., concurring) (for the purpose of class certification, "courts determine the extent of a defendant's monetary liability to the entire class" in the aggregate); *see also* Leitzinger Report ¶ 38.

A class damages model in an antitrust case "need not be exact." *Sanofi Pasteur*, 134 F. Supp. 3d at 849 (citing *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013)); *In re Nexium Antitrust Litig.*, 777 F.3d 9, 17 (1st Cir. 2015) (class certification should not "turn into a 'free-ranging merits inquir[y]' through unnecessary demands for exact calculations of damages") (quoting *Amgen*, 568 U.S. at 466). A "reasonable estimate" of damages is sufficient. *Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 484 (3d. Cir. 1998). "Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victim." *Zenith Radio Corp.*, 395 U.S. at 124.

Dr. Leitzinger explains that aggregate damages can be estimated by classwide formulaic analysis because (1) data regarding actual prices paid, sales volumes, and payor information have been produced by Celgene and dispensing pharmacies (not by individual class members); (2) antitrust

damages are the difference between the average price actually paid by class members and the average price that would have been paid but for Celgene's conduct; (3) the estimated percentage of the class that would convert to generics and the discounted price of a generic is based on common evidence.[178] Similarly, damages caused by Celgene's unjust enrichment can be calculated using the volume of sales protected by the exclusion of generic competition and the incremental profit rate associated with those protected sales.[179] Using the dates that Mr. Molina opines generic entry would have occurred,[180] Dr. Leitzinger performs illustrative formulaic calculations to estimate damages incurred. Within the Antitrust/Consumer Protection Damages Class, Thalomid purchasers incurred between [redacted], and Revlimid purchasers incurred between [redacted] in damages to date, under these illustrations.[181] Within the Unjust Enrichment Damages Class, Thalomid purchasers incurred between [redacted], and Revlimid purchasers incurred between [redacted], in damages to date, under these illustrations.[182]

Through Dr. Leitzinger's overcharge methodology, Plaintiffs have met their burden to demonstrate that "there is a reliable means for measuring damages with reasonable accuracy in the aggregate." *See In re Processed Egg*, 312 F.R.D. at 202-03; *see also Sanofi Pasteur*, 134 F. Supp. 3d at 849

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[178] *See* Leitzinger Report § V "Classwide Analysis of Damages." *See also id.* at ¶ 45 ("Total Overcharge = [Average Actual Price-Average But For Price] x Class Volume[.] That is, total classwide overcharges will equal the difference between average prices actually paid by Class members . . . [for prescriptions involving] the two drugs and the average prices that would have been paid" in the but for world "multiplied by . . . total [purchase] volume").

[179] *See* Leitzinger Report, ¶ 58 ("Unjust Enrichment = Protected Sales x Incremental Profit Rate").

[180] Mr. Molina offers two scenarios for generic entry. First, based on industry standards for the time it typically takes to bring a generic drug to market, Mr. Molina provides conservative dates when generic versions of Thalomid and Revlimid would have been available had Celgene negotiated in good faith with competitors that sought samples. Molina Report at ¶¶ 21, 31-55. Mr. Molina's conservative model allows 2.5 years (30 months) for Celgene's patent infringement claims to be litigated and adjudicated. *See id.* at ¶ 48. Second, given Plaintiffs' allegations that Celgene's patents are invalid and Celgene has engaged in sham litigation to enforce these patents, Mr. Molina also opines on generic entry dates in a "but for" world where Celgene never sought patents on the REMS process, Thalomid, or Revlimid. *Id.* at ¶ 56.

[181] Leitzinger Report, ¶ 57, Exs. 7A-7D.

[182] Leitzinger Report, ¶ 61, Exs. 8A-8D.

(approving Dr. Leitzinger's aggregate classwide damages model).

Indeed, "[r]ecognition that individual damages calculations do not preclude class certification under Rule 23(b)(3) is well nigh universal." *Neale v. Volvo Cars of N. Am.*, 794 F.3d 353, 374-75 (3d Cir. 2015) (citing *Comcast*, 569 U.S. at 42); *Cmty. Bank of N. Va.*, 795 F.3d at 410 (affirming class certification despite potential individualized damage inquiries, noting that "[t]here are imaginative solutions to problems created by the presence in a class action litigation of individualized damages") (internal citations omitted). Any damages awarded on a classwide basis at trial can be apportioned at a later date. *See Lidoderm*, 2017 WL 679367, at *11.

e. There Is Little Variation in the Relevant State Laws

As noted above, any differences between the state law claims are insignificant. *See* Appendix E. In addition to unjust enrichment claims, Plaintiffs have brought state antitrust claims under the *Illinois Brick* "repealer" state jurisdictions.[183] Accordingly, courts have certified end-payor antitrust and/or consumer protection classes defined in this manner. *See, e.g., In re Warfarin*, 391 F.3d at 529-30 (affirming class certification, noting that "recent decisions elsewhere have certified nationwide or multistate classes under state laws in actions alleging overpayment for brand-name prescription drugs") (citing *In re Lorazepam & Clorazepate Antitrust Litig.*, 205 F.R.D. 369 (D.D.C. 2002)).[184]

Here, the Antitrust/Consumer Protection Damages Class and the Unjust Enrichment

[183] *Illinois Brick Co. v. Illinois,* 431 U.S. 720 (1977) held that only direct purchasers could pursue an overcharge claim arising from an antitrust violation. Following this decision, a number of states adopted *Illinois Brick* "repealer" statutes that mirror the Sherman Act, 15 U.S.C. § 1 *et seq.*, but permit indirect purchaser standing. *See, e.g., Union Carbide Corp. v. Superior Court,* 679 P.2d 14, 17 (Cal. 1984). In a 1989 challenge to these "repealer" statutes, the Supreme Court held that federal antitrust laws did not pre-empt state antitrust laws, and that state laws permitting indirect purchasers to receive damages were not in conflict with federal antitrust laws. *California v. ARC Am. Corp.*, 490 U.S. 93, 105-06 (1989).

[184] *See also In re Wellbutrin*, 282 F.R.D. at 145; *In re Nexium,* 297 F.R.D. at 176 (finding variance in state laws and statutes of limitations does not bar class certification); *In re Terazosin*, 220 F.R.D. at 701 ("the Court acknowledges that management of the several state classes will raise numerous challenges. However, these challenges are ones that routinely arise in complex litigation, and they are insufficient to overcome the innumerable advantages that class treatment will afford.").

Damages Class assert claims in the same states. Because the "core elements of the state laws in play are identical," any differences in their application are not material. *See In re Lidoderm*, 2017 WL 679367, at *27. Moreover, Third Circuit "precedent provides that 'variations in the rights and remedies available to injured class members under the various laws of the fifty states [do] not defeat commonality and predominance.'" *Sullivan*, 667 F.3d at 301 (citing *In re Warfarin*, 391 F.3d at 529); *In re Prudential*, 148 F.3d at 310. Indeed, the Third Circuit has even "emphasized [its] willingness to certify nationwide classes where differences in state law fell 'into a limited number of predictable patterns,' and any deviations 'could be overcome at trial by grouping similar state laws together and applying them as a unit.'"[185] *Sullivan*, 667 F.3d at 301 (discussing *In re Prudential*, 148 F.3d at 315); *see also In re School Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir. 1986).

This Court need not find that there is a complete uniformity of state law in order to grant certification—only that there are no material conflicts among the laws such that they can be divided into a manageable number of sub-groups. Here, Plaintiffs have brought damages claims under the laws of fourteen states with virtually identical elements, as illustrated in Appendix E. Given the multitude of common issues shared by class members, any minor variations in state law fail to defeat the predominance requirement.

2. A Class Action Is Superior to Other Available Methods of Adjudication

Rule 23(b)(3) requires that a class action be "superior to other available methods for fairly and efficiently adjudicating the controversy," and provides a "non-exhaustive" list of factors to consider in determining superiority, including: the class members' interest in individually controlling the

[185] As the *Lidoderm* Court noted, from a practical perspective, any state law "differences can be readily accommodated on a special verdict form or through other mechanisms routinely employed in complex litigations like this one." 2017 WL 679367, at *27. *See also Simon v. Phillip Morris Inc.*, 124 F. Supp. 2d 46, 77 (E.D.N.Y. 2000) ("[T]here will never be 50 different substantive rules, or even fifteen or ten. States tend to copy their laws from each other, and many use identical or virtually identical rules. In practice, the court will seldom have to deal with more than three or four formulations.") (internal citation omitted).

prosecution of separate actions; the extent and nature of any similar litigation already commenced by class members; the desirability of concentrating the litigation in a particular forum; and the difficulties likely to be encountered in the management of a class action. Fed. R. Civ. P. 23(b)(3); *Cmty. Bank of N. Va.*, 795 F.3d at 409. To determine whether the requirement is satisfied, a court must "balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication." *Id.* "[S]imilar to the predominance requirement, the requirement of superiority ensures that resolution by class action will 'achieve economies of time, effort, and expense, and promote . . . uniformity of decision without sacrificing procedural fairness or bringing about other undesirable results.'" *Flonase*, 294 F.R.D. at 234 (quoting *Amchem*, 521 U.S. at 615).

The superiority requirement is satisfied in this case. "The interests of efficiency and economy favor litigating the antitrust claims of the thousands of class members, who are widely dispersed geographically, in a single forum. Otherwise, scores of individual lawsuits would rely on similar evidence and proof." *In re Processed Egg*, 312 F.R.D. at 203-04. In end payor class actions alleging generic entry, the "vast majority of district courts" have held that class action treatment is superior to other available methods of adjudication. *Flonase*, 284 F.R.D. at 234; *see also Cardizem*, 200 F.R.D. at 351 ("Multiple lawsuits by the large number of class members allegedly injured by Defendants' antitrust violations would be costly and inefficient").

In addition, this case does not present any greater manageability challenges than other class actions alleging state law claims. Manageability issues pose a barrier to certification only where they create a situation in which the class action is less fair and efficient than other available adjudication techniques. *See In re Cmty. Bank of N. Virginia,* 418 F.3d 277, 309 (3d Cir. 2005); *In re Vitamins Antitrust Litig.,* 209 F.R.D. 251, 270 (D.D.C. 2002) (rejecting defendants' argument that increasing the number of individual lawsuits by denying class certification was more manageable

than a class action).[186] Indeed, any manageability concerns can be addressed as they arise through a variety of case management tools. *See Visa Check*, 280 F.3d at 141 (management tools include bifurcating trials, appointing a magistrate or special master for individual proceedings, decertifying the class after a liability trial and providing notice to class members concerning how they may proceed, creating subclasses, or altering or amending the class). For these reasons, a class action is superior to any alternative method for adjudicating Plaintiffs' claims.

D. CLASS CERTIFICATION IS APPROPRIATE UNDER RULE 23(B)(2)

Rule 23(b)(2) supports class certification when a single injunction would provide cohesive relief to the entire class. Fed. R. Civ. P. 23(b)(2). "When a class seeks an indivisible injunction benefitting all its members at once, there is no reason to undertake a case-specific inquiry into whether class issues predominate or whether class action is a superior method of adjudicating the dispute. Predominance and superiority are self-evident." *Wal-Mart*, 564 U.S. at 362-63; *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 143 (3d Cir. 1998) ("While 23(b)(2) class actions have no predominance or superiority requirements, it is well established that the class claims must be cohesive.").

The Court should certify the Injunction Class, which seeks to restore the market to the natural competitive equilibrium that would exist but for Celgene's ongoing anticompetitive conduct.[187] Where a defendant engages in a common course of conduct toward plaintiffs, there is "no need for *individualized* determinations of the propriety of injunctive relief." *Baby Neal*, 43 F.3d at 57 (emphasis in original) ("(b)(2) classes have been certified in a legion of . . . cases where commonality

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[186] "[F]ailure to certify an action under Rule 23(b)(3) on the sole ground that it would be unmanageable is disfavored and should be the exception rather than the rule." *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 141 (2d Cir. 2001) (internal citations omitted); *In re Prudential Ins. Co. of Am. Sales Practices Litig.,* 962 F. Supp. 450, 525 (D.N.J. 1997) ("[M]ost courts hold that manageability difficulties cannot support denial of class certification when no other practical litigation alternative exists.").

[187] "[C]laims for injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, do not undermine *Illinois Brick*, but rather fall properly outside its scope." *In re Relafen Antitrust Litig.*, 221 F.R.D. at 273; *Mid-W. Paper Prods. Co. v. Cont'l Grp., Inc.*, 596 F.2d 573, 589 (3d Cir. 1979).

findings were based primarily on the fact that defendant's conduct is central to the claims of all class members"). Celgene's scheme to foreclose generic competition has distorted competitive market forces and caused end-payors to pay supracompetitive prices for thalidomide and lenalidomide. Absent court intervention, this harm will continue. Thus, because all members of the Injunction Class face the same threat of injury from Celgene's violation of the antitrust laws,[188] and injunctive relief would benefit the class as a whole, class certification is warranted under Rule 23(b)(2).

E. APPOINTMENT OF CO-LEAD COUNSEL

Rule 23(g) provides that "[u]nless a statute provides otherwise, a court that certifies a class must appoint class counsel," and it sets out the factors a court should consider in doing so.[189] Interim co-lead counsel have substantial experience in the prosecution of complex litigation cases, including antitrust class actions on behalf of indirect purchasers, and they have demonstrated a willingness and ability to dedicate the resources and expertise necessary to fairly and adequately represent a class of plaintiffs and successfully manage a class action to its conclusion. ECF No. 66. The Court previously appointed the proposed co-lead counsel as Interim Co-Lead Counsel, *see* ECF No. 92 (Apr. 4, 2016), and they have committed substantial resources in prosecuting this action to date and will continue to do so. Thus, Interim Co-Lead Counsel are highly qualified to represent the Classes and request that they be appointed as Co-Lead Counsel.

F. CONCLUSION

Based on the foregoing, Plaintiffs respectfully request that this Court certify the proposed

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[188] "To establish the need for injunctive relief, plaintiffs must generally demonstrate three uncomplicated prerequisites: 'a threat of loss'; that the injury in question 'is of the type the antitrust laws were intended to prevent'; and 'a significant threat of injury from a violation of the antitrust laws.'" *Sullivan*, 667 F.3d at 317 (*en banc*) (citing *In re Warfarin*, 596 F.2d at 399).

[189] *See* Fed. R. Civ. P. 23(g)(1) ("(A) must consider: (i) the work counsel has done in identifying or investigating potential claims in the action; (ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action; (iii) counsel's knowledge of the applicable law; and (iv) the resources that counsel will commit to representing the class [and] (B) may consider any other matter pertinent to counsel's ability to fairly and adequately represent the interests of the class.").

Classes identified herein and appoint Interim Co-Lead Counsel as Class Counsel.

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